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MARY HELEN SEARS
THE M H SEARS LAW FIRM CHARTERED
910 SEVENTEENTH STREET NW
SUITE 800
WASHINGTON, DC 20006

EXAMINER	
PORTNER, VIRGINIA ALLEN	
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1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/397,110	Applicant(s) Moore et al
	Examiner Portner	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Nov 21, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-9 and 33-54* is/are pending in the application.

4a) Of the above, claim(s) *1-9* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *33-54* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-9 and 33-54* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Claims 10-32 have been canceled.

Claims 1-9 and 33-54 are pending.

Allowable Subject Matter

1. Claims 33, 35-44, 47 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Election/Restriction

2. Claims 1-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups I-IV and VII, there being no allowable generic or linking claim.

3. Newly submitted claims 33-54 will be examined together in view of Applicant's arguments made of record in paper number 8, which read on Groups V and VI of the original Election/Restriction requirement. The Election/Restriction requirement is deemed proper and made Final.

Claim Objections

4. Claim 50 is objected to because of the following informalities: On line two the word "containg" is recited. It appears this word should be --containing--. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 33-49, 52-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 recites in step e) the phrases "conducting an assay upon a liquid sample" and "which assay comprises the step of detecting the C-polysaccharide cell wall antigen of Streptococcus pneumoniae". Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: providing a sample, a detection reagent and correlating the presence of a signal with the presence of S.pneumoniae antigen. The antibodies purified over the column contained not more than 10% protein and would bind antibodies directed to S.pneumoniae antigens that are not C-polysaccharide binding antibodies. The antibodies of

step d) are any S.pneumoniae antibodies and were not produced to a composition of purified polysaccharide but must only be antibodies that bind to S.pneumoniae. The specificity of the purified antibodies is defined through the recitation of " purified antigen specific antibodies" but the antigen is not limited to C-polysaccharide binding specificity. While section e) refers to the antibodies of section (d), the reagent is presented in the passive voice, and the only methods step required to be carried out is "detecting the C-polysaccharide". Clarification of the claimed invention is requested.

Claim 33, section e), line six recites the ~~phase~~ phrase "which may in part be conjugated to a tag". What part of the antibodies is conjugated and what part is not conjugated? What relationship does the tag part have with the untagged part? What is the detectable physical change that is effected? What is the chemical change that the antibodies effect?

7. The term "essentially comprise" in claims 33-48 is a relative term which renders the claim indefinite. The term "essentially comprises" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear what the detection agent is, if it is not the antibodies? What is the detection agent that "essentially comprises purified antigen-specific antibodies"? How can a composition "essentially comprise" something? What does the composition comprise? What does it consist essentially of? Clarification of the phrase "essentially comprise" is requested relative to the detection agent?

Claim 34 depends from claim 32 which has been canceled. The invention of claim 34 is not distinctly claimed.

Claim 37 recites the phrase "fluid sample". The word "fluid" lacks antecedent basis in claim 36 which recites the term "liquid". Amendment of claim 37 to recite the term "liquid" could obviate this rejection.

Claims 40 and 49 recites the phase "developed meningitis". What is developed meningitis as compared to meningitis? Amendment of the claims to recite just the term "meningitis" would distinctly claim applicant's invention.

Claim 41 defines step e) to be an immunoassay process and depends from claim 33. What are the process steps of the immunoassay of claim 41? What other processes are encompassed by the "conducting" step e) of claim 33, if it is not an immunoassay? If claim 33 is intended to encompass more detection assays other than just immunoassays, what reagents are being used? Are the antibodies for the immunoassay process of claim 41 different from the antibodies obtained in the method of claim 33? Clarification is requested?

Claim 42 depends from claim 40 and defines step (e) to be an immunochromatographic process. Claim 40 does not provide any chromatographic materials for carrying out an immunochromatographic process, nor do claims 39, 35 or 33 define the needed material for carrying out an immunochromatographic process. A clarification step does not define an active voice methods step. The assay of claim 33 is any assay that will detect C-polysaccharide cell wall antigen and is not limited to an immunoassay. How does the process of claim 42 differ from the

assay of claim 33? Amendment of the claim to recite the phrase --further comprising-- together with providing the needed materials for this type of immunoassay could possibly obviate this rejection.

Claim 43 depends from claim 33 and recites the phrase "in which step (e) is conducted by". Claim 33 already recites the phrase "conducting an assay" and "which assay comprises the step of detecting". It appears that claim 43 intends to substitute the method steps recited in claim 43 for the single methods step of claim 33. Claim 43 does not recite a detecting step that is recited in claim 33. Clarification is requested.

Claim 43, section d) recites the step of "within". This is not an active voice methods step. This section also recites the phrase "observing whether a line of color". Where did the color come from? What is producing the color? How is the line produced? How can any line of color be indicative of the presence of Streptococcus pneumoniae?

Claim 45 is dependent upon itself and does not recite any methods steps. The claim does not distinctly claim Applicant's invention.

Claims 46,48-49 depend from claim 45. The invention is not distinctly claimed for the same reasons set forth above for claim 45.

Claim 50 section b) recites the phrase "for viewing color changes". What produces the color changes? What is the color changed from/to? How is the color that changes produced?

Claim 51 defines the labeling agent to be "finely divided metallic gold" and depends from claim 50. Gold is known to produce a reddish/violet color. How does this color change? What takes place to change the color?

Claims 52-54 are dependent upon claim 49, which is indirectly dependent upon claim 45. None of the claims from which claims 52-54 depend recite an "ICT" device. The phrase "of the ICT device of claim 49" lacks antecedent basis in claim 49. Claim 49 depends from claim 45 which defines the sample to be urine. The "strip of bibulous material" lacks antecedent basis in claim 49. The invention is not clear or distinctly claimed.

Claim 52, section b) recites the phrase "said test strip". This phrase lacks antecedent basis in the claim and the claim from which it depends. This section also recites the phrase "movably embedded conjugate of labeling agent". No labeling agent has been provided. What is the labeling agent? What is the antigen for which the antibodies are specific? No antigen has been specifically defined in the claims. No specific antigen is recited in the claim from which it depends.

Claim 52, section c) recites the phrases "entrained conjugate" and "said test". These phrases lack antecedent basis and have not been clearly defined. No test or entrained conjugate have been provided as an assay system or reagent on the bibulous material. How did the conjugate get entrained? The only material provided is a bibulous strip. The strip is not defined to have reagents immobilized thereto, nor is it defined to have zones of reagents as a test system.

Claim 52 recites in section d) the phrase "observing through the view window whether a line of color has appeared, indicating the presence in the test sample of Streptococcus pneumoniae and/or its cell wall C-polysaccharide antigen." Is the colored line always indicative of a positive test? Where did the color come from? Could a negative test have a colored line with a gold label? How is a colored line from a negative test and a colored line from a positive test differ? A colored particulate label (gold metallic label) will always produce color through the view window, how would one distinguish one from the other viewed through the window?

Claims 52-54 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: first and second antibodies in the bibulous material. The bibulous material is the only material contacted with the sample. The bibulous material is not required to have immobilized antibodies in a zone. A "where it" phrase does not define the presence of a reagent that has not been provided.

Claim Rejections - 35 U.S.C. § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 50-51(Streptococcus pneumoniae) are rejected under 35 U.S.C. 102(b) as being anticipated by Imrich (US Pat. 5,415,994) in light of Gribnau et al (US Pat. 4,373,932, incorporated by reference in Imrich).

(DEVICE) The claimed invention is directed to a device that comprises:

a housing;

first and second zones; wherein the first zone comprises a labeling agent (species recited in claim 51: gold) conjugated to purified antibodies that bind to Streptococcus pneumoniae and the second zone comprises a second antibody that also binds to Streptococcus pneumoniae; and

a window in the housing.

(Claim 50) Imrich teaches an immunochromatographic lateral flow device wherein the device comprises:

a housing (see front of patent),

a bibulous strip material (see Imrich col. 4, lines 56-63) that contains first and second zones (see col. 4, lines 64-65), and

a window(see Imrich col. 7, line 16) in the housing (see Imrich, figure 3, 4, 5a and 5b) through which to view test results.

The first zone would comprises an analyte first antibody labeling agent (see Imrich, col. 5, lines 28-38) specific to Streptococcus pneumoniae antigen, and the second zone comprises a

second antibody that captures the Streptococcus pneumoniae antigen/first antibody complex (see col. 7, lines 63-65, second antibody binds to the antibody labeled antigen analyte)) through binding thereto.

(Claim 51) The first antibody labeling agent is taught to comprise a metallic gold sol (see Imrich col. 5, line 33) , in light of US Pat. 4,373,932(incorporated by reference, col. 2, line 45). The labeling agent is conjugated (bound) to purified antibodies (see Imrich, col. 5, lines 16-20) that specifically bind to Streptococcus pneumoniae (see Imrich col. 7, line 2).

Inherently the reference anticipates the now claimed invention.

Please Note: The following art rejections are being made of record in view of the method claims 52-54, not reciting any specific reagents immobilized on the bibulous material, and claim 52 depending from a claim that does not recite an ICT device.

10. Claims 52-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Imrich (US Pat. 5,415,994).

(METHOD) The claimed invention is directed to a method of detecting Streptococcus pneumoniae in a sample utilizing an immunochromatographic test device. The method comprising the steps of :

(**clm52**) **contacting** the sample with a bibulous material;

allowing the liquid sample to flow laterally (title);

allowing the liquid sample and the entrained conjugate to flow laterally; (see Imrich col. 5, lines 46-52) ,

observing whether a line of color has appeared (see figure 3), wherein the line of color is indicative of Streptococcus pneumoniae infection(see col. 3, lines 9-21 and claims)

(**Clm53**) liquid sample of natural mammalian origin (human/ mammalian samples, col. 1, line 33:patients).

(**Clm54**) liquid sample is urine, spinal fluid or sputum. (see Imrich, col. 3, lines 10-14);

Inherently the reference anticipates the now claimed invention.

11. Claims 52-54 are rejected under 35 U.S.C. 102(b) as being anticipated by May et al. (METHOD) The claimed invention is directed to a method of detecting Streptococcus in a sample utilizing an immunochromatographic test device.

May et al teach a method comprising the steps of:

(Clm52) **contacting** the sample with a bibulous material (page 8, lines 20-22; page 2, line 13);

allowing the liquid sample to flow laterally (allowed to permeate, page 2, lines 12-13);

allowing the liquid sample and the entrained conjugate to flow laterally (sample progresses, page 2, line 15; page 4, lines 15-22; page 6, lines 1-14; page 10, lines 1-13);

observing whether a line of color has appeared (see figure 3, a line of color would form in a positive test, and no line of color would form in a negative test).

(Clm53) liquid sample of natural mammalian origin (see page 7, line 27).

(Clm54) liquid sample is urine (see page 7, line 27).

Inherently the reference anticipates the now claimed method.

Claim Rejections - 35 U.S.C. § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 50-51 (C-polysaccharide antigen species) are rejected under 35 U.S.C. 103(a) as being unpatentable over Imrich (US Pat. 5,415,994) in light of Gribnau et al (US Pat. 4,373,932, incorporated by reference in Imrich, col. 5, line 37) in view of Krook et al (1987).

(DEVICE) The claimed invention is directed to a device that comprises:

a housing;

first and second zones; wherein the first zone comprises a labeling agent (species recited in claim 51: gold) conjugated to purified antibodies that bind to Streptococcus pneumoniae and/or C-polysaccharide antigen and the second zone comprises a second antibody that also binds to Streptococcus pneumoniae C-polysaccharide antigen; and

a window in the housing.

Imrich teaches an immunochromatographic lateral flow device and method of using the device, wherein the device comprises:

a housing (see front of patent),

a bibulous strip material (see Imrich col. 4, lines 56-63) that contains first and second zones (see col. 4, lines 64-65), and

a window(see Imrich col. 7, line 16) in the housing (see Imrich, figure 3, 4, 5a and 5b) through which to view test results.

The first zone would comprises an analyte first antibody labeling agent (see Imrich, col. 5, lines 28-38) specific to Streptococcus pneumoniae antigen, and the second zone comprises a second antibody that captures the Streptococcus pneumoniae antigen/ entrained conjugate first antibody complex (see col. 7, lines 63-65, second antibody binds to the antibody labeled antigen analyte)) through binding thereto.

The liquid/fluid samples analyzed by the immunochromatographic device include urine, cerebrospinal fluid, nasal secretions, pharyngeal exudates and sputum (see col. 3, lines 10-14).

The first antibody labeling agent is taught to comprise a metallic gold sol (see Imrich col. 5, line 33 , in light of US Pat. 4,373,932, incorporated by reference, col. 2, line 45). The labeling agent is conjugated (bound) to purified antibodies (see Imrich, col. 5, lines 16-20) that specifically bind to Streptococcus pneumoniae (see Imrich col. 7, line 2).

Imrich shows the formulation of an immunochromatographic test strip device for the determination of Streptococcus pneumoniae in a fluid sample (see col. 3, lines 9-21 and claims) that comprises first and second zones that contain antibodies to Streptococcus pneumoniae (see Imrich all claims) and is rapid (see col. 2, line 13, as well as documents incorporated by reference at col. 3, lines 39-48) , but differs from the instantly claimed invention by failing to show the antibodies to be specific to S. pneumoniae C-polysaccharide antigen.

Krook et al show affinity purified polyclonal antibodies and a monoclonal antibody specific to S. pneumoniae C-polysaccharide antigen in an analogous art for the purpose of showing the antibodies used in a two antibody immunoassay for detection of S. pneumoniae C-polysaccharide in a patient sample for detecting the presence of S.pneumoniae and/or C-polysaccharide cell wall antigen.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the device of Imrich to utilize antibodies specific for C-polysaccharide antigen of Krook et al because Imrich teaches the importance of detecting S.pneumoniae in a patient sample and Krook et al teaches S.pneumoniae specific antibodies that are specific and sensitive for detecting S.pneumoniae and/or C-polysaccharide antigen, and Imrich et al teaches a device that carries out a rapid immunoassay format that minimizes operator performance time (Imrich, col. 2, line s 12-13), provides means for diluting a sample prior to assay, filtration of a sample before analysis, and extraction of a sample prior to detection of the desired antigen (Imrich, col. 3, lines 18-21).

In the absence of a showing of unexpected results the person of ordinary skill in the art would have been motivated by the reasonable expectation of success because Krook et al teach the C-polysaccharide specific antibodies were able to detect the presence of S.pneumoniae antigen in a patient sputum sample and the incorporation of the antibodies of Krook et al into the device of Imrich would provide a means for detecting Streptococcus pneumoniae, a human pathogen, and/or C-polysaccharide antigen, an antigen shown to be associated with infection in a rapid(see Imrich et al, col. 6, line 68 and col. 7, lines 2-10).

14. Claims 50-51 (C-polysaccharide antigen species) are rejected under 35 U.S.C. 103(a) as being unpatentable over May et al (WO88/08534) in view of Krook et al (1987).

(DEVICE) The claimed invention is directed to a device that comprises:

a housing,

first and second zones,wherein the first zone comprises a labeling agent (species recited in claim 51: gold) conjugated to purified antibodies that bind to Streptococcus pneumoniae C-polysaccharide antigen and the second zone comprises a second antibody that binds to the Streptococcus pneumoniae C-polysaccharide antigen/first labeled-antibody complex; and

a window in the housing,

May et al teaches a device and a method of using the device, wherein the device comprises a housing (see front of patent);

a window (see figure 3) in the housing;

a bibulous strip material that contains first and second zones (see figures), wherein the first zone comprises an anti-streptococcus first antibody labeling agent (see page 14, lines 15-24) and the second zone (see page 11, lines 29-34) comprises a second antibody (see page 29, lines 4-13) that captures (see page 16, lines 1-8) the Streptococcus antigen/labeling antibody complex (an entrained conjugate; see page 17, line 10).

The first antibody labeling agent is taught to comprise a metallic gold sol (see page 10, lines 1-13). The labeling agent is conjugated (coupled) to purified antibodies (see page 10, lines 29-31) that specifically bind to the desired analyte, ie. Streptococcus. The test result is observable in ten minutes or less (see page 2, lines 6-7).

May et al shows the formulation of an immunochromatographic test strip device that comprises first and second zones that contain antibodies to Streptococcus for the determination of Streptococcus antigen, in a fluid sample, but differs from the instantly claimed invention by failing to show the antibodies to be Streptococcus pneumoniae C-polysaccharide antigen.

Krook et al show affinity purified polyclonal antibodies and a monoclonal antibody specific to S. pneumoniae C-polysaccharide antigen in an analogous art for the purpose of showing the antibodies used in a two antibody immunoassay for detection of S. pneumoniae C-polysaccharide in a patient sample and detection of infection.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the device of May et al to utilize antibodies specific for Streptococcus C-polysaccharide antigen of Krook et al because Krook et al teaches

Streptococcus antibodies able to detect the presence of Streptococcus pneumoniae C-polysaccharide antigen in a biological sample, May et al teaches the importance of detecting Streptococcus antigen to assist in diagnosis of infection (see page 17, line 10, and lines 16-18) and the device of May et al provides means for a rapid immunoassay format that minimizes operator performance time (see May, page 2, lines 6-7, 10 minutes or less and page 2, lines 33-34).

In the absence of a showing of unexpected results the person of ordinary skill in the art would have been motivated by the reasonable expectation of success of detecting Streptococcus infection utilizing the Streptococcus pneumoniae anti-cell wall polysaccharide C antibodies of Krook et al because Krook et al teach the C-polysaccharide specific antibodies were able to detect the presence of Streptococcus antigen in a patient sputum sample and the incorporation of the antibodies of Krook et al into the device of May et al would provide a means for diagnosing a human pathogen rapidly in an outpatient setting, requiring the user to perform as few action as possible (see page 2, lines 33-34).

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

16. Brown et al, Sand et al, Rubenstein, Eisinger et al, Sippel et al, Stuertz et al (1998), Holmberg et al (1985), Gillespie et al (1995), and Koskela et al (1992) are cited to show means

and methods of obtaining antigen, antibodies and methods of detecting Streptococcus antigen, to include polysaccharide antigens.

17. Rehg et al (US Pat. 6,194,221) is cited to show an immunochromatographic device for detection of Streptococcus antigens (see claims).

18. Friesen et al (RE37,437 and 4,861,711) are cited to show that heterogenous immunoassays are readily adapted to immunochromatographic assay formats that are faster.

19. Gillespie et al (1994) is cited to show an immunoassay for the detection of C-polysaccharide (teichoic acid) of Streptococcus pneumoniae in saliva and urine.

20. Havas et al (1984) is cited to show methods of active and passive immunization of a mammal with Streptococcus pneumoniae antigen or antigen binding antibodies, respectively.

21. Holmberg et al (1985) is cited to show an immunoassay for C-polysaccharide of Streptococcus pneumoniae.

22. Laferriere et al (1997) is cited to show C-polysaccharide antibodies, a method of purifying C-polysaccharide, purified C-polysaccharide and an immunoassay for C-polysaccharide of Streptococcus pneumoniae.

23. Parkinson et al (1992) is cited to show an immunoassay for the detection of C-polysaccharide of Streptococcus pneumoniae in sputum (see title).

24. Rosen et al (1996) is cited to show antibodies to C-polysaccharide in milk.

25. Sundberg-Kovamees et al (1996) is cited to show antibodies, a method of purifying C-polysaccharide, purified C-polysaccharide and an immunoassay for C-polysaccharide for Streptococcus pneumoniae.

26. Stuertz, K et al (1998); Sridharan, G et al (1994) and Yolken, RH et al (1984) are cited to show an immunoassay for the detection of C-polysaccharide (teichoic acid) of Streptococcus pneumoniae in cerebrospinal fluid (see title).

27. Sjogren et al (1987) is cited to show cross reactivity of C-polysaccharide of Streptococcus pneumoniae with other oral microorganisms.

28. Sjogren et al (1987) is cited to show monoclonal and polyclonal antibodies, as well as an immunoassay for C-polysaccharide of Streptococcus pneumoniae using the antibodies.

29. Westphal et al (1965) is cited to show an extraction method for bacterial polysaccharides.

30. Yolken et al (1984) is cited to show an immunoassay for the detection of pneumococcal antigen in cerebrospinal fluid.

31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp
February 11, 2002

L. F. Smith
LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600